IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

HUMAN GENOME SCIENCES, INC.,	)	
	)	
Plaintiff,	)	C.A. No. 11-156-LPS
	)	
v.	)	
	)	
GENENTECH, INC.,	)	
	)	
Defendant.	)	

OPENING BRIEF IN SUPPORT OF DEFENDANT GENENTECH, INC.'S MOTION TO DISMISS OR STAY

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

HGS' complaint is a carbon copy of a lawsuit filed against Genentech eight years ago. That case was summarily adjudicated in Genentech's favor, and the Federal Circuit affirmed, holding that it did not state a claim to begin with. If precedent means anything, this case should likewise be dismissed.

The earlier case was *MedImmune, Inc. v Genentech, Inc. et al.*, 2:03-cv-02567 MRP (C.D. Cal. Apr. 11, 2003) ("*MedImmune*") and was assigned to Judge Pfaelzer. MedImmune is another biotech company that, like HGS, practices the "Cabilly II patent." In 2003, MedImmune sued Genentech for violations of the Sherman Act and related state claims contending, as HGS now alleges, that actions taken and agreements made in settling an interference between Genentech and Celltech R&D Inc. caused the Patent Office to issue the Cabilly II patent to Genentech. The similarity of the MedImmune and HGS allegations is nearly absolute:

- *MedImmune*: "MedImmune has filed this action to challenge an illegal and anticompetitive agreement (the "Agreement") between Genentech and Celltech, two large biotechnology companies, which has the effect of creating a 29-year patent monopoly over what Genentech now claims is the 'fundamental technology' required for the artificial synthesis of antibody molecules." Request for Judicial Notice ("RJN"), Ex. 1, *Medimmune*, First Amended Complaint (hereinafter "FAC") at ¶9.
- *HGS*: "[T]his case relates fundamentally to a collusive and anti-competitive scheme between Genetech and Celltech R&D Ltd. ("Celltech") to create by agreement and enforce a *29-year patent monopoly* over what Genentech claims is the 'fundamental technology' for the artificial synthesis of potentially life-saving therapeutic antibodies, allegedly embodied in" the Cabilly II patent. Compl., D.I. 1 at ¶1.

In 2004, Judge Pfaelzer held that the allegedly collusive scheme between Genentech and Celltech was foreclosed by the *Noerr-Pennington* doctrine, which bars antitrust suits based on petitioning activity that allegedly causes the government to take anticompetitive actions. She reasoned that it was the issuance of the Cabilly II patent that was the proximate cause of any

injury to MedImmune, not the settlement agreement. RJN, Ex.2, *MedImmune*, Am. Mem. of Decision, dated January 15, 2004 . The Federal Circuit affirmed in *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958 (Fed. Cir. 2005), holding that quite apart from *Noerr-Pennington* immunity, the parties' conduct related to the settlement simply was not an antitrust violation.

Judge Pfaelzer and the Federal Circuit also addressed a *Walker Process* fraud claim that MedImmune advanced to try to save its antitrust case, and which HGS has also copied with only minor variations. RJN, Ex. 2 at 18-19; 427 F.3d at 967. Judge Pfaelzer denied MedImmune leave to amend its complaint to advance these fraud claims, in part because the substantive allegations—mostly identical to HGS'—did "not ple[a]d facts sufficient to support *Walker Process* fraud." RJN, Ex. 3, *MedImmune*, Mem. of Decision at 6-8. The Federal Circuit affirmed that ruling as well, finding that the fraud allegations left MedImmune "without a reasonable likelihood of supporting a claim of antitrust violation. . . ." 427 F.3d at 968.

There are only a handful of minor factual differences between the allegations in this case and the allegations of the MedImmune case. HGS should not be allowed to pursue what binding Federal Circuit precedent forecloses.

II. NATURE AND STAGE OF PROCEEDINGS

The Complaint was filed on February 18, 2011. Curiously, HGS filed it as a separate lawsuit from HGS' other anticipatory lawsuit, *Human Genome Science, Inc. v. Genentech, Inc.*, C.A. 82-LPS (D. Del.) ("*HGS I*"), which was filed against Genentech and City of Hope ("COH") on January 25, 2011, and seeks declaratory relief that the Cabilly II patent is invalid and unenforceable. Genentech filed a motion, which has been fully briefed in this Court, to transfer *HGS I* to Judge Pfaelzer. RJN, Ex. 4. Genentech is concurrently filing a motion to consolidate this case with *HGS I* so that it can be transferred to Judge Pfaelzer as well.

III. ARGUMENT

A motion to dismiss under Rule 12(b)(6) tests the factual and legal sufficiency of a complaint. A plaintiff must allege sufficient "factual matter" to state a claim to relief, and where the pleaded facts "do not permit the court to infer more than the mere possibility of misconduct,"

the complaint will be found insufficient. *Ashcroft v. Iqbal*, __ U.S. __, 129 S. Ct. 1937, 1949 (2009). The pleaded facts must also be legally sufficient in the sense that they show entitlement to relief under the governing substantive law. "If the plaintiff does plead particulars, and they show he has no claim, then the plaintiff has pleaded himself out of court." 5 Wright & Miller, Federal Practice & Procedure § 1215 (3d ed. 2009).

A. HGS' Allegations Concerning the Allegedly Unlawful Settlement Agreement Have Already been Found Deficient by the Federal Circuit and Should be Dismissed.

1. HGS' Conspiracy Allegations are Identical to Those Considered and Rejected in *MedImmune*.

The first cause of action in HGS' Complaint alleges a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, which prohibits a "combination, contract or conspiracy" in restraint of trade. Section 1 requires concerted action by two or more parties; unilateral action is entirely outside the scope of Section 1. *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984) ("Section 1 of the Sherman Act . . . does not reach conduct that is 'wholly unilateral.'"). HGS' second cause of action alleges a "conspiracy to monopolize" under Section 2 of the Sherman Act, 15 U.S.C. § 2, which also requires concerted action. *United States v. Yellow Cab Co.*, 332 U.S. 218, 225 (1947), *overruled on other grounds by Copperweld Corp., supra.* All Section 1 and Section 2 claims are subject to dismissal if the only concerted action pled is not unlawful. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 553 (2007) (Section 1); Areeda & Hovenkamp, Antitrust Law, ¶ 809 (3d ed. 2010) ("there can be no 'conspiracy' to monopolize in the absence of a qualifying agreement").

The only concerted conduct to which HGS points, and the alleged root cause of its injury, is the settlement agreement between Genentech and Celltech. This is *exactly* the conspiracy theory that was alleged and rejected in *MedImmune*. Every major theme and every minor step in the story is exactly the same:

Both complaints begin with the history of the Boss and Cabilly I patents, how they were issued on the same day, that Genentech provoked an interference, that Boss was accorded status as the senior inventor, and that the PTO resolved the interference in favor of Boss. (Compl., D.I.

1 at ¶13; FAC ¶31). See comparison table attached hereto as an Appendix.

Both complaints allege that Genentech commenced a federal district court action under 35 U.S.C. §146 (the "146 Action") to review the PTO's decision,[1] and that during the 146 Action, Genentech discovered an earlier draft of the Cabilly patent application, and based on that evidence thereafter moved for summary judgment. (Compl., D.I. 1 at ¶25-29; FAC ¶30-32).

Both complaints allege that the arguments on Genentech's summary judgment motion created a risk to patentability, in that Celltech's efforts to discredit the Draft Cabilly II application called into question the Boss patent. (Compl., D.I. 1 at ¶¶32, 38-40; FAC ¶¶34, 53-60) Celltech and Genentech therefore allegedly had a shared motive to settle the case. (Compl., D.I. 1 at ¶33; FAC ¶35).

Both complaints allege that to ensure patentability and reap the benefits of the additional years of patent exclusivity that Genentech would enjoy were it to prevail, Celltech falsely conceded priority. Celltech was allegedly compensated with "reverse payments," *i.e.*, royalty payments from Genentech to Celltech during Genentech's patent term. (Compl., D.I. 1 at ¶¶34, 47; FAC ¶38)

Finally, both complaints allege that Genentech and Celltech entered into an anticompetitive settlement agreement pursuant to which they asked the District Court to enter an order that Genentech was entitled to priority, that proposed findings in support of the order were inconsistent with arguments made by the parties in their summary judgment papers, that the District Court signed the settlement order without substantive changes, and that this is how the PTO was compelled to revoke the Boss patent and issue the Cabilly II patent. (Compl., D.I. 1 at ¶53; FAC ¶42).[2]

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[1] The 146 Action was brought in the Northern District of California before Judge Chesney. *Genentech, Inc. v. Celltech Therapeutics, Ltd.*, Case No. C-98-3926 MMC (N.D. Cal. Oct. 9, 1998).

[2] Like MedImmune, HGS also tries to make something out of alleged irregularities in the way Genentech filed the settlement of the interference with the PTO pursuant to 35 U.S.C. § 135(c). Judge Pfaelzer and the Federal Circuit rejected that argument as well. RJN, Ex. 2 at 4; 427 F.3d 968.

It is no wonder that when *The American Lawyer* asked MedImmune's antitrust counsel to comment on HGS' case, he said: "It sounds like the same suit we brought."[3]

2. The Federal Circuit Has Held that the Genentech-Celltech Settlement Does Not Violate Antitrust Law.

In *MedImmune,* the Federal Circuit considered the claim that HGS makes here and held that neither the settlement itself nor the joint petitioning that followed violated the Sherman Act. Noting that settlement of patent interferences can appropriately "expedite resolution of difficult issues," the court held that neither "[a] joint communication to a court of the terms of settlement of a matter before the court, [nor] a joint petition to the PTO to implement the court's judgment, are ... actions that would be prohibited or tainted" by the Sherman Act. 427 F.3d at 966-67. To the contrary, the parties were legally obliged both to submit their settlement to the court and to submit the court's order to the PTO. *Id.* The Federal Circuit's conclusion was unambiguous: "The joint request of the litigants that the PTO implement the judgment is not a prohibited collusion." *Id.* Because the Federal Circuit did not accept that the allegedly "collusive settlement" was an antitrust violation to begin with, it did not even reach the alternative grounds of *Noerr-Pennington* immunity on which Judge Pfaelzer had granted summary judgment. *Id.*

The Federal Circuit also addressed and rejected MedImmune's argument—that HGS repeats—that the fact that the parties had allegedly misrepresented who was entitled to priority when presenting the settlement to the district court showed unlawful collusion. The Federal Circuit disagreed, holding that "disputed issues from the underlying litigation cannot be recast as misrepresentations." It added: "MedImmune's disagreement with the result of the priority settlement does not convert it into a presumptive violation of the antitrust laws, or grant MedImmune standing to require judicial review of the evidence and the conclusion reached in the settlement." *Id.* The Federal Circuit noted that the position MedImmune (and HGS) advocate "can discourage if not prevent settlements, placing unnecessary burdens on the courts and the PTO." *Id.* at 966.

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[3] Alison Frankel, *New Antitrust Complaint Against Genentech Raises Ghost of 2007 Supreme Court Loss,* The AmLaw Litigation Daily (Feb. 24, 2011).

The Federal Circuit's ruling did not depend on the resolution of particular facts; it was a conclusion that the conduct at issue here—settling an interference proceeding, submitting that settlement to the court for approval, and submitting the court's ruling to the PTO to be implemented—can't violate the antitrust laws. The fact that the Federal Circuit—to which any appeal from this Court would run[4]—has rejected the allegations that are the sole basis for a claim of conspiracy in restraint of trade mandates dismissal of the first and second causes of action.

3. The District Court Decision in *MedImmune* Establishes that Genentech's Actions in Petitioning to Have the Settlement Terms Implemented Were Protected by the *Noerr-Pennington* Doctrine.

When Judge Pfaelzer addressed MedImmune's antitrust allegations, she presumed that a settlement agreement could violate antitrust law, but then found that the attack on this settlement agreement was grounded on efforts to petition the government—the district court and the PTO—that was protected "petitioning" under the *Noerr-Pennington* doctrine. RJN, Ex.2 at 10-11.

The *Noerr-Pennington* doctrine protects efforts to petition the government, including the courts, even if the resulting governmental action in some sense restrains competition. In so doing, it ensures that antitrust and other laws do not unreasonably burden the constitutional right to petition, and that courts do not inappropriately inquire into what causes governmental entities to act in particular ways. *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 137-38 (1965); *United Mine Workers of Am. v. Pennington,* 381 U.S. 657, 671 (1965) (plaintiff could not recover "for any injury which it suffered from the action of the Secretary of Labor"). The latter point recognizes that when petitioning succeeds, "the injury of which the antitrust plaintiff complains was proximately 'caused' by the government itself." 1 P. Areeda and H. Hovenkamp, Antitrust Law ¶ 202c at 159. Thus, the injury is not the legal responsibility of those who petitioned for the restraint. *Andryx Pharm., Inc. v. Biovail Corp. Int'l,* 256 F.3d 799, 818 (D.C. Cir. 2001) ("If anticompetitive harm is caused by the decision of a court, even though granted at the request of a private party, no private restraint of trade occurs because the

[4] *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1067-68 (Fed. Cir. 1998) (*Walker Process* claims invoke the Federal Circuit's exclusive jurisdiction); *MedImmune*, 427 F.3d at 968-69 (refusing to transfer the antitrust case against Genentech to the Ninth Circuit).

intervening government action breaks the causal chain.").

Judge Pfaelzer thoroughly addressed the application of *Noerr-Pennington* to the facts alleged by HGS and held that it foreclosed any attack on the Genentech-Celltech settlement agreement. RJN, Ex. 2. She noted that the parties' private actions—their settlement and the petitioning that followed—did not in itself restrain trade. Rather, the alleged "anti-competitiveness of the agreement depended on the government exercising its independent power to decide priority and issue the New Cabilly patent." *Id.* at 15. That necessitated two efforts to obtain governmental action: (1) to the district court, to get a judgment of priority, and then (2) to the PTO, which needed to accept the mandate of the district court, resolve any remaining patent issues, and issue the desired patent. *Id.* at 11. Judge Pfaelzer found "that petitioning was involved in each of these two steps," and consequently that "the *Noerr-Pennington* doctrine protects the Defendants from antitrust liability." *Id.* at 10-11.

MedImmune advanced numerous arguments to escape *Noerr-Pennington* immunity, every one of which is echoed in HGS' complaint. RJN, Ex. 5, Medimmune's Mem. of P. & A. in Opp'n to Def. Celltech's Mot. for J. on the Pleadings and Def. Genentech's Mot. for Summ. J. Judge Pfaelzer rightly rejected them all; we highlight two.

Genuine Petitioning: MedImmune tried to argue that presenting a consent judgment to the judge overseeing the 146 action, with stipulated factual findings, was not "genuine petitioning." Judge Pfaelzer disagreed. She found:

> The Defendants in this case did not merely present their settlement to Judge Chesney for approval; they sought a Judgment and an Order as well. The documents that she signed accomplished results, such as overturning the Board's priority decision, that could not have been accomplished through private agreement. It was these documents - the results of the Defendants' petitioning and Judge Chesney's order - that resolved the issue of priority.

RJN, Ex. 2 at 15. Judge Pfaelzer also rejected MedImmune's efforts to question whether the district court that approved the settlement "reached a 'considered, substantive judgment,' (to use MedImmune's phrase)," because *Noerr-Pennington* prohibits "deconstructing the decision-

making process" of a governmental actor. *Id.* at 15-16.[5]

Misrepresentations: Judge Pfaelzer carefully considered and rejected MedImmune's argument that when the settling parties told the court overseeing the 146 Action that Genentech's New Cabilly Patent had priority over the Boss patent, they made a misrepresentation that destroyed *Noerr-Pennington* protection. RJN, Ex. 2 at 14-17. Judge Pfaelzer recognized that a party cannot establish misrepresentation by "simply recast[ing] disputed issues from the underlying litigation as 'misrepresentations' by the other party," *Kottle v. Nw Kidney Ctrs*, 146 F.3d 1056, 1063 (9th Cir. 1998), and that this was true of the "misrepresentations" MedImmune alleged and HGS repeats: calling one side of a disputed issue "false." As she put it, "any settlement agreement had to make a representation one way or the other on [priority] and that representation was sure to be contradictory to a position that one of the parties had taken earlier in the litigation." RJN, Ex. 2 at 16-17. The Federal Circuit endorsed that view. 427 F.3d at 967.[6]

In short, the harm of which HGS (and previously, MedImmune) complains proximately results not from alleged collusion between the parties, but from two discretionary acts by government officials: Judge Chesney's decision to accept the consent judgment and award priority to Genentech, and the PTO's decision to substantively examine the patent after priority was determined – and subsequently issue the patent. RJN, Ex. 6-8. Because participating in the settlement agreement and the petitioning to those government decision-makers are the only collusive acts alleged in HGS' complaint, both its first and second causes of action must be dismissed.

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[5] It should be noted that the consent judgment reversing the Board's priority determination was hardly a *pro forma* request. It proposed the ultimate relief available in a § 146 action. Courts not only have the discretion to deny such requests, they have done so. *Brunswick Corp. v. Riegel Textile Corp.*, 1986 U.S. Dist. LEXIS 25949 (N.D. Ill. May 2, 1986) (declining to enter proposed consent judgment reversing Board).

[6] Moreover, Judge Pfaelzer's ruling was decided under Ninth Circuit authority which permits inquiry into whether misrepresentations during litigation "deprive the litigation of its legitimacy." *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1060 (9th Cir. 1998) (citation omitted). The Third Circuit has expressly rejected this view. *See Armstrong Surgical Ctr., Inc. v. Armstrong Cty. Mem'l Hosp.*, 185 F.3d 154, 164 n.7 (3rd Cir. 1999).[6]

B. The Third Cause of Action Should be Dismissed For Failure to State a Claim; at a Minimum, the Bulk of its Allegations Should be Stricken as Legally Insufficient to Support the Relief Sought.

HGS' third cause of action alleges monopolization under Section 2 of the Sherman Act. It incorporates the collusive settlement story, but in the context of alleging that Genentech unilaterally monopolized a licensing market. The additional alleged unilateral conduct is *Walker Process* fraud and "sham" litigation for pursuing claims based on a patent known to be unenforceable, invalid, and not infringed.

This too is a repeat of the *MedImmune* case. MedImmune tried to save its antitrust claim by alleging a *Walker Process* violation during the PTO process that followed the Genentech-Celltech settlement. FAC ¶¶79, 88, 96, 100. Indeed, all but one of the statements or behaviors that HGS says constitute *Walker Process* fraud were advanced by MedImmune and considered and rejected by Judge Pfaelzer and the Federal Circuit. *See* RJN, Ex. 2 at 18-19; 427 F.3d at 967. With respect to these allegations, the only material difference between this case and MedImmune is that HGS is starting with allegations MedImmune added to the case over time.

1. The Majority of HGS' *Walker Process* Theories Are Barred by the Decisions in *MedImmune*

Four of the five basic fraud allegations contained in HGS' complaint are identical to MedImmune's fraud claims.

First, both allege that Genentech did not focus the PTO on the supposed enablement issue created by Celltech's contention before the District Court that the Draft Cabilly application did not disclose a workable method of refolding certain proteins. Compl., D.I. 1 at ¶¶63-67; FAC 68; 73-74.

Second, both allege that Genentech took inconsistent positions with regard to the Valle reference before the PTO and the European Patent Office (EPO), and failed to point out to the PTO the position it had taken in the EPO. Compl., D.I. 1 at ¶69-71; FAC 79-91.

Third, both accuse Genentech of "dumping" 350 prior art references, including 275 in one day alone, on the PTO (Compl., D.I. 1 at ¶73; FAC ¶92), without highlighting for the PTO any particular references (Compl., D.I. 1 at ¶74; FAC ¶94), including the Stanford patent

(Compl., D.I. 1 at ¶¶75-77; FAC ¶¶96-98).

Fourth, both accuse Genentech of failing to disclose the supposedly critical Axel patents at all. Compl., D.I. 1 at ¶¶78-80; FAC ¶¶100-103. In particular, both complaints allege that Genentech must have been aware of the Axel patents because it was paying royalties on them (Compl., D.I. 1 at ¶79; FAC ¶93).

HGS alleges only one instance of misconduct before the PTO that MedImmune did not previously (and unsuccessfully) allege. HGS claims that the Cabilly II patent does not disclose the best mode known to the inventors at the time the application was filed, and relatedly that the experiments described in the patent had not been performed exactly as described. Compl., D.I. 1 at ¶¶82-85. HGS did not lift this allegation from *MedImmune*, but it is not new either. HGS lifted it from allegations made by Centocor in *Centocor, Inc. v. Genentech, Inc., and City of Hope Natl. Med. Ctr.*, Case No. 2:08-cv-03573 MRP (C.D. Cal. May 30, 2008) ("*Centocor*"), another case involving the Cabilly II patent which Judge Pfaelzer has presided over during the past 8 years. RJN, Ex. 9, *Centocor*, Second Am. Compl. for Declaratory J.

With respect to the four allegations taken from *MedImmune*, Judge Pfaelzer's analysis and conclusion that "MedImmune has not pled facts sufficient to support *Walker Process* fraud" are sound and should be followed. RJN, Ex. 2 at 19. Judge Pfaelzer focused on the fundamental difference between fraud and inequitable conduct, as outlined by the Federal Circuit in *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998). There the Federal Circuit held:

> A finding of *Walker Process* fraud requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct. Moreover, unlike a finding of inequitable conduct, ... a finding of *Walker Process* fraud may not be based upon an equitable balancing of lesser degrees of materiality and intent. Rather, it must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, *i.e.* that the patent would not have issued but for the misrepresentation or omission.

141 F.3d at 1070-71 (internal citations omitted).

Judge Pfaelzer held that MedImmune's fraud allegations, which fundamentally consist of

three quibbles about references that *were disclosed* and one routine nondisclosure allegation, "suggest neither independent or clear evidence of deceptive intent nor that the patent would not have issued but for the misrepresentation or omission (i.e. reliance)." RJN, Ex.2 at 21-22. In particular, she noted that MedImmune's three "failure to highlight" and/or "dumping" allegations—the enablement/refolding issue, the Valle reference, and the Stanford reference—could not state a *Walker Process* claim as a matter of law because all of those references (and the district court documents from the 146 Action disclosing the parties' positions on the refolding issue) had been before the PTO, which is presumed to be aware of what is presented to it. *Id.* Indeed, as she noted, "[e]ven inequitable conduct cannot be found on the basis of a reference that was cited to the examiner." *Id.* at 22.[7]

As to the Axel Patents, Judge Pfaelzer considered the same fraud story that HGS retells and concluded that the facts would not "support a finding of fraudulent intent." *Id.* at 22. *Nobelpharma* holds that a mere failure to cite a reference will not support a claim for *Walker Process* fraud. *Nobelpharma*, 141 F.3d at 1071; *see also C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998) (deceptive intent is not inferred simply because information was in existence that was not presented to the examiner). Thus, even putting aside the fact that Genentech in fact *disclosed* the lead Axel patent to the PTO during the interference,[8] Judge Pfaelzer was right to hold that mere nondisclosure allegations are insufficient. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 375 F.3d 1312, 1327 (Fed. Cir. 2009) ("[Federal Circuit] precedent . . . requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind.").

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[7] For this reason alone, HGS' allegations concerning enablement/refolding, Valle, and the Stanford patent should at a minimum be stricken, as they cannot support HGS' claims as a matter of law. *See Symbol Techs., Inc. v. Aruba Networks*, Inc., 609 F. Supp. 2d 353, 356, 358-59 (D. Del. 2009) (striking accused infringer's inequitable conduct defense based on the alleged "burying" of a reference because "burying" cannot support a defense of inequitable conduct).

[8] RJN, Ex. 16, Decl. of Dr. Richard Axel at ¶7. Genentech also disclosed the companion article. US Patent No. 6,331,415 B1 (issued Dec. 18, 2001) at page 7 (citing Wigler *et al.*, "Transformation of Mammalian Cells with Genes from Procaryotes and Eucaryotes" *Cell* 16:777-785 (Apr. 1979)).

Judge Pfaelzer was forced to revisit all of this when, in response to her grant of summary judgment, MedImmune moved for leave to amend, proffering an allegedly new and improved *Walker Process* claim. *See* RJN, Ex. 3 at 6-7 (internal citations and quotations omitted).[9] Judge Pfaelzer denied leave to amend on multiple grounds, but most important for present purposes is her decision that amendment would be futile. *Id.* at 6-7. She explained that the bulk of MedImmune's factual allegations remained unchanged, and that the addition of conclusory language labeling the alleged misconduct as "fraudulent" didn't matter. Under the substantive law, "[t]hey did not constitute *Walker Process* fraud then [before the word "fraud" was added], and they do not support a fraud claim now." *Id.*

MedImmune appealed the decision denying leave to amend on both the substantive and procedural grounds. In the words of the Federal Circuit, "the parties . . . in their briefs discussed at some length the prosecution aspects challenged by MedImmune." 427 F.3d at 968. The Federal Circuit affirmed Judge Pfaelzer on all counts, holding that "[t]he district court correctly held that the pleadings, which charged Genentech with inequitable conduct, not fraud, fell short of alleging a *Walker Process* antitrust violation." *Id.* at 967. The court added: "we discern no error in the district court's determination that MedImmune was without a reasonable likelihood of supporting a claim of antitrust violation. . . ." *Id.* at 968.

2. The "Best Mode" Allegation Fails to Allege Fraud

The only thing left to consider is HGS' "best mode" allegation. Compl. , D.I. 1 at ¶¶82-89. The allegations fail on the face of HGS' complaint. The gist of the false statement or omission alleged by HGS is that (a) in order "to achieve optimal results – and the results reported in the patent" certain parameters had to be followed; (b) different (allegedly sub-optimal) parameters were disclosed in the patent; and (c) the correct (optimal) parameters were set forth in inventors' notebooks and described in declarations later submitted by the inventors. Compl., D.I. 1 at ¶¶83-84. But the very documents HGS cites to show the supposedly undisclosed optimal

[9] The opinion was written before the "no set of facts" language of *Conley v. Gibson* was retired by the Supreme Court's decision in *Twombly*.

parameters – pages from an inventor's notebook and certain inventors' declarations – *were themselves disclosed to the PTO before the patent issued.* RJN, Ex. 10, Affidavit Under C.F.R § 1.131; Ex. 11, Decl. of Ronald Wetzel; Ex 12, Decl. of Jeanne Perry. That makes this just another flavor of the "failure to highlight" claims that were deemed insufficient in MedImmune. *See* RJN Ex. 2 at 22, citing *American Hoist*, 725 F.2d at 1359; *Intermatic Inc. v. Lamson & Sessions Co.*, No. 94C50295, 1999 WL 181980, at * 3 (N.D. Ill. March 30, 1999) ("[Plaintiff] makes much of the fact that the PTO is busy and does not have time to wade through the morass of paper associated with patent applications, and that [Defendant] capitalized on this. Absent proof to the contrary, courts presume an examiner has considered the references."); *Applied Materials v. Advanced Semiconductor Materials Am.*, 30 U.S.P.Q. 2d 1967, 1969 (N.D. Cal. Apr. 19, 1994*), aff'd* 104 F.3d 376 (Fed. Cir. 1996) ("Once the Hart patent was before the patent examiner, he was presumed to have considered it."). Furthermore, "citation as prior art defeats [the] charge that [a reference] was withheld with deceptive intent." *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1582 (Fed. Cir. 1991) ("When a reference was before the examiner . . . it cannot be deemed to have been withheld from the examiner.").

In short, HGS should not be allowed to advance fraud claims that are either the same as or no better than those rejected in *MedImmune*. The third cause of action should be dismissed.

3. HGS' Sham Litigation Allegations Also Fail

HGS is advancing a so-called "sham litigation" claim that, under the circumstances alleged in the complaint, is wholly without basis. The Complaint begins with protests about how, with the Cabilly II patent, Genentech has "successfully exclud[ed] or obtaine[ed] licenses from virtually all competitors seeking to compete in various downstream product markets." Compl., D.I. 1 at ¶6. It recounts a part of the long history by which Genentech obtained the patent, which involved unusually extensive review by the PTO and even a reexamination proceeding. HGS then turns around and says that Genentech's efforts to enforce the patent are a "sham," invoking an antitrust doctrine that requires proof that an actual or threatened lawsuit is

so "objectively baseless that no reasonable litigant could realistically expect success on the merits." *Prof'l Real Estate Investors v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993) ("*PREI*"). It makes no sense that Genentech could get this hotly contested patent in the first place, and then "successfully exclud[e] or obtain[] licenses from virtually all" who want to practice it, if the patent is so weak the *no one* could reasonably believe an enforcement action could succeed.

The Supreme Court has set forth a two-prong test for determining whether litigation is a "sham" such that a patentee should not be entitled to *Noerr-Pennington* immunity. *See PREI*, 508 U.S. at 49. The first prong is that "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Id.* at 60. If, but only if, the first prong is established, the court turns to "the second, subjective prong, *i.e.*. whether the 'baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use [of] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon.'" *Magnetar Techs. Corp. v. Six Flags Theme Parks Inc.*, C.A. No. 07-127-LPS, 2011 WL 678707, at *2 (D. Del. Feb. 18, 2011) (quoting *PREI*, 508 U.S. at 60-61). HGS' complaint fails both prongs.

First, HGS' entire case with respect to objective baselessness is simply a rehash of the preceding antitrust issues. They are, in short, arguments—and nothing more. Some theories have already failed in other litigation; others are being litigated before Judge Pfaelzer. But the mere existence of these arguments does not meet HGS' burden to show that Genentech's position in these cases is objectively baseless. Genentech has prevailed in an intense, years-long reexamination process in the PTO, of which the Court may take judicial notice.[10] RJN, Exs.7 & 8. And HGS admits that Genentech has enjoyed considerable success licensing the patent, which is a powerful indication that Genentech's claim are not a sham. *Cf. PREI,* 508 U.S. at 60 n.5 ("[a] winning lawsuit is by definition ... not a sham").

[10] *See* Genentech's Request for Judicial Notice in Support of its Motion to Dismiss or Stay, filed contemporaneously herewith.

In all events, there is absolutely no claim to be made here that Genentech is trying to use "the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991) ("*Omni*"). In patent suits against others, Genentech enforces its patent rights as Congress envisioned, and it seeks the remedies that patent law provides. *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1576 (Fed. Cir. 1990) ("Congress has specifically granted patent owners the right to commence a civil suit in order to protect their inventions."). Applying the dichotomy established in *Omni*, this litigation is an "outcome of [the] process" case, not one involving the kind of direct interference with a competitor's business needed to establish sham litigation. The sham litigation theory thus also fails.

C. HGS Fails To State a Claim for Violation of the Lanham Act

The Lanham Act prohibits certain false or misleading statements made "in commercial advertising or promotion." 15 U.S.C. § 1125(a)(1)(B). That is, Lanham Act claims are typically false advertising claims. There is no hint of false advertising in HGS' allegations. Instead, HGS alleges that unspecified statements Genentech made "in a variety of earnings calls, press releases, financial filings, and other public statements" are Lanham Act violations because the patent is not really valid, enforceable or apparently ever infringed. Compl., D.I. 1 at ¶200.

HGS has failed to plead a Lanham Act violation with the required particularity. Lanham Act cases recognize that to defend against false statement claims, "it is important that the party charged be provided with sufficiently detailed allegations regarding the nature of the alleged falsehoods.'" *Wellness Publ'g v. Barefoot*, No. 02-3773, 2008 WL 108889, at *15 (D.N.J. Jan. 8, 2008) (quoting *Max Daetwyler Corp. v. Input Graphics, Inc.*, 608 F. Supp. 1549, 1556 (E.D. Pa. 1985)). The courts have thus adopted an "'intermediate' approach" for pleading Lanham Act false advertising claims," something "between application and outright rejection of Rule 9(b)." *Id.* at *15 (citation and quotation omitted). Under this approach, a complaint, like the one filed by HGS, that "neither identifies nor provides any detail at all regarding the alleged misstatements" is insufficient and will be dismissed. *Id.* No specific statements are identified

and there is next to no detail about anything.[11]

More fundamentally, the federal courts have shown little patience with efforts like this one to convert patent suits into Lanham Act cases. Accordingly, a strict bad faith standard applies, that permits "the imposition of liability for publicizing a patent in the marketplace" only where "the plaintiff can show that the patent holder acted in bad faith," and the "bad faith" standard "cannot be satisfied in the absence of a showing that the claims asserted were objectively baseless." *Dominant Semiconductors SDN. BHD. v. Osram GmbH*, 524 F.3d 1254, 1260 (Fed. Cir. 2008); *Zenith Elecs. Corp., v. Exzec, Inc.*, 182 F.3d 1340, 1353 (Fed. Cir. 1999) ("before a patentee may be held liable under § 43(a) for marketplace activity in support of its patent, and thus be deprived of the right to make statements about potential infringement of its patent, the marketplace activity must have been undertaken in bad faith").

Here, HGS has not pled, and has no basis to plead, that any statement Genentech made in the marketplace about the Cabilly II patent was objectively baseless. The Cabilly II patent is presumptively valid. Genentech has been successful before the PTO on reexamination and through claim construction in the *MedImmune*, *Centocor, and GSK* matters, and many companies have taken licenses to the patent. The outcome in all completed cases to date has been a settlement, not a decision that the Cabilly II patent was not valid, not enforceable or not infringed. *See* RJN, Ex. 13, M*edImmune* Stipulation and Order of Dismissal; Ex. 14, *Centocor* Stipulation of Dismissal of Entire Action with Prejudice; Ex. 15, *Centocor* Order of Dismissal of

[11] At best, HGS references three statements: (1) a press release issued by Genentech on December 18, 2001, generally describing the manner in which the Cabilly II patent issued and explaining that it relates to "fundamental methods and compositions used to produce antibodies by recombinant DNA technology" (Compl., D.I. 1 at ¶¶94, 200); (2) a statement made by Genentech's then-Vice President of Intellectual Property, in February 2002, that the Cabilly II patent "broadly covers the co-expression of immunoglobulin heavy and light chain genes in a single host cell [and that] [w]e do not believe that the claims are limited by type of antibody (murine, humanized, or human) or by host cell type" (Compl., D.I. 1 at ¶¶128, 200); and (3) a statement made by Genentech in 2009 in another litigation that the methods claimed in the Cabilly II patent are "the backbone of recombinant antibody production in the biotech industry." *See* Compl., D.I 1 at ¶¶128, 200. Yet even as to those three statements, HGS does not explain why they are false or why it has any basis to believe that other elements of a Lanham Act claim, such as reliance, are met.

Entire Action with Prejudice. That history is more than enough to establish that Genentech has a good faith basis for making positive public statements about the Cabilly II patent. *Dominant Semiconductors SDN. BHD.*, 524 F.3d at 1261-62, ("[W]hen an underlying infringement suit *was not unsuccessful,* there is no basis to determine that the plaintiff in that suit lacked probable cause") (emphasis added).

Nor does HGS' baseless claim that it will win its invalidity challenge save HGS' Complaint. Bad faith and objective baselessness are determined at the time a statement is made. Thus, "[e]ven if a patent was obtained through fraud and even if upon examination, a court would invalidate that patent, until such a determination of invalidity is made, the patent is considered valid and enforceable. As such, . . . statements as to the contemporaneous existence of the patent are true and are not misleading." *IMCS, Inc. v. D.P. Tech. Corp.*, 264 F. Supp. 2d 193, 197 (E.D. Pa. 2003); *see also, e.g.*, *ISCO Int'l, Inc. v. Conductus, Inc.*, 279 F. Supp. 2d 489, 506 (D. Del. 2003), *aff'd* 123 F. App'x 974 (Fed. Cir. 2005).

D. Plaintiff's State Law Claims Should Be Dismissed

Plaintiff also asserts claims for relief under the Delaware Uniform Deceptive Trade Practices Act ("DTPA"), and pursuant to common law principles of unfair competition, tortious interference with prospective business opportunity, and civil conspiracy. Because Plaintiff has failed to state a claim for relief under federal law, the Court may decline to exercise supplemental jurisdiction over HGS' state law claims. *Wiers v. Barnes*, 925 F. Supp. 1079, 1089 (D. Del. 1996) ("If the federal claims are disposed of prior to trial, the non-federal claims should likewise be dismissed. If the Court chooses to address the merits, however, Plaintiff's state law claims should be dismissed for failure to state a claim.

1. HGS Fails to State a Claim for Statutory Unfair Competition, Tortious Interference, or Common Law Unfair Competition

The DTPA "prohibits conduct that disparages the goods, services, or business of another by false or misleading representation of fact or that generally creates a likelihood of confusion or of misunderstanding." *Accenture Global Services GmbH v. Guidewire Software Inc.*, 581 F. Supp. 2d 654, 665(D. Del. 2008). The elements of the common-law claims for tortious

interference with prospective business opportunities and unfair competition under Delaware law are in all material respects identical. *See, e.g., Kent Cty. Equip., Inc. v. Jones Motor Group, Inc.*, No. 08C-04-030 JAP, 2009 WL 737782, at *3 (Del. Super. Ct. March 20, 2009). The alleged conduct underlying HGS' DTPA and common law unfair competition claims is the same as that underlying its asserted claim under the Lanham Act and fails for the same reasons.

All three claims fail because all three require the same showing of objective baselessness and bad faith required for the Lanham Act claim – a showing that HGS has not and cannot make. *See Monsanto Co. v. Syngenta Seeds, Inc.*, 443 F. Supp. 2d 648, 653 (D. Del. 2006) (DPTA parallels Lanham Act); *Accenture*, 581 F. Supp. 2d at 666, 668 n.19 (bad faith required for DTPA claim based on statements concerning patent infringement); *Mikhon Gaming Corp, v. Acres Gaming, Inc.*, 165 F.3d 891, 894 (Fed. Cir. 1998) (tortious interference and common law unfair competition claims must be assessed consistently with federal patent law).

2. HGS Fails to State a Claim of Civil Conspiracy

The touchstone of a conspiracy claim is an unlawful agreement. *See AeroGlobal Capital Mgmnt., LLC v. Cirrus Indus., Inc.*, 871 A.2d 428, 437 (Del. 2005). As explained above, the settlement agreement – which is the only conspiracy alleged in the complaint – was lawful and thus cannot form the basis of a civil conspiracy claim.

E. Alternatively, this Case Should Be Stayed On All Non-Patent Issues

In the alternative, the Court should bifurcate HGS' antitrust and patent claims and stay the antitrust issues (including discovery), pending resolution of the patent issues, pursuant to Fed. R. Civ. P. 42(b), under which courts consider "whether bifurcation will avoid prejudice, conserve judicial resources, and enhance juror comprehension of the issues presented in the case." *Enzo Life Sciences, Inc. v. Digene Corp.*, C.A. No. 02-212-JJF, 2003 WL 21402512, at *4 (D. Del. June 10, 2003). Each factor supports bifurcation here.

The Federal Circuit has long approved sequentially deciding patent and antitrust issues:

> Moreover, it is clear that the present separation order was appropriate for the same reasons listed in the cases Abbott cites: (1) Economy is served because in the trial of the patent issues the validity of the patent and Innotron's affirmative defenses will be determined and will become law of the case and thus removed

> from trial on the original antitrust issues; (2) Convenience of all is served in trying the less complex patent issues first; (3) Expedition is served because the patent issues on the present schedule will be ready for trial more than a year before the antitrust issues can be made ready; (4) Avoidance of prejudice and confusion is served in trying first the patent issues, without injecting the different counterclaim issues which require different proof and different witnesses.

In re Innotron Diagnostics, 800 F.2d 1077, 1085 (Fed. Cir. 1986) (footnote omitted). Bifurcating and staying antitrust issues from patent issues has been and remains "standard practice." *Innotron*, 800 F.2d at 1084; *Eurand, Inc. v. Mylan Pharm., Inc.*, C.A. No. 08-889-SLR, 2009 WL 3172197 (D. Del. Oct. 1, 2009) (same); *Masimo Corp. v. Philips Elecs. N. Am. Corp*, C.A. No. 09-80-LPS, 2010 WL 3909969, at * (D. Del. Oct. 6, 2010) ("Bifurcation ... is not mandatory, but is common.").

1. Efficiency and Convenience Favor Resolving the Patent Claims First.

The antitrust and tort claims depend on HGS' contention that the patent is invalid, unenforceable, or not infringed. If HGS loses those arguments, it loses on the merits, without the need for the expenditure of further resources by the parties or the Court. HGS' *Walker Process* theory requires it to show that the Cabilly II patent would not have issued but for alleged misrepresentations, *i.e.* to show by clear and convincing evidence that the Cabilly II patent is invalid. *See Nobelpharma AB,* 141 F.3d at 1070. This Court therefore should stay HGS' *Walker Process* claims pending resolution of validity.

The additional antitrust issues presented here will require the Court to supervise discovery and decide a wide variety of issues, potentially including the definition of two alleged markets (an "upstream technology market" and a "downstream product market"), the extent of competition in each market, other existing barriers to entry, and the alleged anticompetitive effects of the alleged conduct. *See Twombly*, *supra*, 550 U.S. at 558-59 (noting complexity and burden of antitrust discovery, and cautioning courts not "to forget that proceeding to antitrust discovery can be expensive"); *Masimo Corp.*, 2010 WL 925864, at * 2 (same).

2. Bifurcation and Staying of Antitrust Discovery Will Avoid Prejudice

HGS must prove Genentech's subjective motivation for asserting patent infringement to

show "sham litigation." Discovery into subjective motivation invades the attorney-client privilege, since the decision whether to assert claims is informed by legal advice. But subjective motivation is wholly irrelevant, and discovery into it is properly denied, unless and until HGS can demonstrate that Genentech's claims were *objectively baseless*. *PREI*, 508 U.S. at 57. Thus, to allow such discovery to proceed now, when HGS has not made—and will never be able to make—any such showing, would fundamentally prejudice Genentech, by forcing it to decide whether to waive privilege and rely on advice of counsel or assert privilege but forego a powerful defense. Deferring such discovery unless HGS can establish objective baselessness avoids prejudice.

3. Trying All Issues Together Poses a Risk of Juror Confusion and Bias.

Forcing the jury to consider complex economic and market issues while simultaneously struggling through complicated biotechnology issues will create significant juror confusion. *Innotron*, 800 F.2d at 1086 ("[T]he potential for jury confusion would be lessened ... by separate trials on the patent and antitrust issues."); *Abraxis*, 2008 WL 2967034, at *8 (same). Additionally, HGS' "allegations of monopolization could bias the jury when it evaluates [HGS's] patent claims." *Masimo Corp.*, 2010 WL 925864, at *2 (internal citation omitted).

IV. CONCLUSION

For the foregoing reasons, Genentech requests the Court to dismiss the case or, in the alternative, to stay it pending the resolution of *HGS I*.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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